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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,081	07/28/2005	Gunter Schmid	008310-000002	8551

30565 7590 08/18/2010

Woodard, Emhardt, Moriarty, McNett & Henry LLP
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EXAMINER	
SHOMER, ISAAC	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
08/18/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketDept@uspatent.com

Office Action Summary	Application No.	Applicant(s)	
	10/523,081	SCHMID ET AL.	
	Examiner	Art Unit	
	ISAAC SHOMER	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-55 and 61-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-55 and 61-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 11 May 2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

This case has been transferred to a new examiner. See the "Conclusion" section below.

Claim Rejections - 35 USC § 102(b)

For the purposes of examination under prior art, the examiner interprets the phrase "formulated for the therapeutic treatment of neoplastic diseases" as reading on any composition that has a therapeutic effect against cancer, whether this therapeutic effect is recognized or not. For example, a preparation consisting of the chemotherapeutic agent rapamycin with no excipients would be considered as reading on the limitation "formulated for the therapeutic treatment of neoplastic disease." This would be the case whether rapamycin was taught for the intended use of cancer treatment, or for a different intended use such as immune suppression.

For the purpose of examination under prior art, the term "a triphenylphosphine radical" of claim 50 will be interpreted as reading on the ligand $P(C_6H_5)_3$. Also, the terminology Au-55 refers to a cluster of 55 gold atoms, not a radioisotope of gold.

Claims 50-55 and 63 stand rejected under 35 U.S.C. 102(b) as being anticipated by Hainfeld et al. (US Patent 5,360,895).

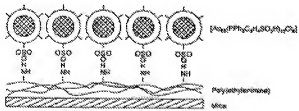
In applicant's arguments dated 11 May 2010 (hereafter referred to as applicant's arguments), applicant contends that Hainfeld et al. (hereafter referred to as Hainfeld) is drawn to gold cluster conjugates comprising antibodies useful as antitumor agents, as of applicant's arguments, page 6, first two paragraphs in Hainfeld section. Applicant argues that the gold-cluster $Au_{55}[PPh_3]_{12}Cl_6$ is an intermediate for the preparation of the final product of Hainfeld, which comprises antibody fragments, as of applicant's arguments, page 6 last paragraph, and applicant reiterates the process by which the final product is made from intermediates, as of applicant's arguments, page 7. Applicant argues that Hainfeld teaches away from using the formulations comprising unmodified triphenylphosphine ligands for treatment, as Hainfeld is alleged to teach that said compounds must be derivatized, as of applicant's arguments, paragraph bridging pages 7 and 8.

In response, the examiner does not necessarily disagree that Hainfeld does not recognize the cluster $Au_{55}[PPh_3]_{12}Cl_6$ as being useful therapeutically as an anti-cancer treatment. However, it is the examiner's position that $Au_{55}[PPh_3]_{12}Cl_6$, which is formulated as a dry solid as of Hainfeld, column 20 lines 9-12, would have been formulated for the treatment of cancer, despite applicant's arguments to the contrary. The fact that this cluster was not recognized for anti-cancer use does not overcome the rejection, as something which is old does not become patentable upon the discovery of a new property, and the inherent feature need not be recognized at the time of the

invention. See MPEP 2112(I) and 2112(II). When the structure taught by the prior art is substantially identical to that of the claims, the claimed properties are presumed to be inherent. See MPEP 2112.01(I). In this case, the structure $Au_{55}[PPh_3]_{12}Cl_6$ was taught by Hainfeld, and as such would be expected to inherently possess the same anti-cancer properties. Applicant has not pointed to anything specific about the formulation of $Au_{55}[PPh_3]_{12}Cl_6$ which would have rendered it unsuitable for therapeutic use. Furthermore, applicant's arguments of "teaching away" are unpersuasive. Arguments that the alleged anticipatory prior art is nonanalogous art' or teaches away from the invention' or is not recognized as solving the problem solved by the claimed invention, [are] not germane' to a rejection under section 102. See MPEP 2131.05.

Claims 50-55 and 61-62 are rejected rejected under 35 U.S.C. 102(b) as being anticipated by Peschel et al. (Angew Chem Int Ed Engl., Vol. 34 No. 13/14, 1995, p. 1442) as evidenced by Rembaum (US Patent 4,013,507).

Peschel et al. (hereafter referred to as Peschel) teaches the salt $Au_{55}\{P\text{-}Ph_2(meta\text{-}C_6H_4SO_3Na)\}$, as of Peschel, page 1442 right column, second full paragraph. Said salt is formulated with polyethyleneimine, as shown by Peschel, Figure 2, as reproduced below.



Peschel does not recognize medical uses of the above complex (e.g. Peschel does not recognize that the size, electronegativity, or stabilization of said complex allows interaction with DNA under physiological conditions). However, there does not appear to be a structural difference between the prior art and the claimed invention. The examiner evidences Rembaum, as Rembaum teaches that the formulation of active agent 3,3-ionene bromide with polyethyleneimine followed by injection into a mouse had a toxicity toward tumor cells, as of Rembaum, column 11 lines 25-28. As such, the skilled artisan would have recognized that formulating an active agent with polyethyleneimine is an appropriate formulation for cancer treatment, even if this property was not recognized by Peschel. Furthermore, the salt $Au_{55}\{P\text{-}Ph_2(meta\text{-}C_6H_4SO_3Na)\}$ is the same as that disclosed by the instant specification as the stabilization energy appears to be an intrinsic property of the above complex and of DNA (as of the equation on page 9 line 35 of the specification) and as the compound of Peschel is disclosed by the specification on page 14 line 20. Something which is old does not become patentable upon the discovery of a new property. See MPEP 2112(I).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ISAAC SHOMER whose telephone number is (571)270-7671. The examiner can normally be reached on 8:00 AM - 5:00 PM Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/I. S./
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612